

**REMARKS**

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks

**Status of the Claims**

Claims 23-40 are now present in this application. Claims 23, 30, 31, 39 and 41 are independent.

Claims 1-22 were previously canceled, claim 41 has been added, and claims 23, 30, 31, 38 and 39 have been amended.

No new matter has been added with the changes to the claims. For instance, claims 23, 31 and 39 are amended by limiting the subject matter of "substantially free," and are based on the disclosure on page 18, lines 9-12 in the present specification. Applicants add that the subject matter of "free of peroxide" and "free of a bleaching agent or a peroxide" is based on page 3, lines 16 to page 4, lines 6 and page 4, lines 29-35 in the specification. Furthermore, claims 23, 31 and 39 are amended by incorporating the language "said ingredient (B) ... by water in saliva", and the mentioned amendments have support at page 8, lines 7-10 and page 11, lines 15-23 in the specification. New claim 41 has support in the various claims and original claim 1.

Reconsideration of this application, as amended, is respectfully requested.

**Claim Objections**

Claims 23-40 are objected as stated in the Office Action at page 2. The informalities have been addressed. Thus, withdrawal of this objection is respectfully requested.

**Issues Under 35 U.S.C. § 112, 1st Paragraph (Written Description)**

Claims 30 and 38 stand rejected under 35 U.S.C. § 112, 1st Paragraph (Office Action, pages 2-3). This rejection is respectfully traversed.

The Examiner is rejecting the recitation of “formed polyethylene”. However, this was a typographical error, and the disputed claims now refer to “foamed polyethylene”. Applicants also note, e.g., paragraph [0054] at page 19, lines 12-13 of the present specification.

Reconsideration and withdrawal of this rejection are respectfully requested.

**Issues Under 35 U.S.C. § 112, 2nd Paragraph**

Claims 23-40 stand rejected under 35 U.S.C. § 112, 2nd Paragraph (Office Action, pages 3-4). This rejection is respectfully traversed.

While not conceding to the Examiner’s interpretation of “substantially free,” the disputed claim language has been replaced with a recited water content. Thus, Applicants respectfully submit that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

**Issues under 35 U.S.C. § 103**

Claims 23-40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Oniki et al. (WO 03/030851), wherein U.S. Application No. 10/491,191 is provided as a English language translation, in view of Takeda et al. (US 2001/0007652) (Office Action, pages 4-7). This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

**The Features and Advantages of the Present Invention**

A whitening method for reversibly making teeth look white by changing the optical properties of the enamel without using any peroxide was proposed by the present inventors in Oniki et al. (WO 03/030851). According to this method, the patient really feels that his or her teeth becomes white. Unfortunately, a drawback of Oniki et al. method was that the whitening effect did not last long. Such a problem with the Oniki et al. method of the whitening effect not lasting for a long time is also mentioned at page 2 of the present specification. The present inventors have proceeded with an investigation to improve the above-described method. As a result, Applicants have made the present invention.

An object of the present invention is to provide a tooth whitening set and a method for reversibly making teeth look white by changing the optical properties of the enamel without using any peroxide, thereby making teeth apparently look white while permitting teeth to restore their original color in the presence of water from saliva and keeping the whitening effect over a long period of time.

In the present invention, as is disclosed at page 8 and page 11 of the present specification, the ingredient (B) is used for preventing the tooth whitening ingredient, which has penetrated into the enamel, from leaching out of the enamel. As a result, the tooth whitening effect lasts longer and is thus an improvement over Oniki et al. That is, in the present invention, the composition contains the ingredient (B) which is dissolved in the tooth whitening ingredient and penetrates into the interrod substance (interstices of the enamel rod) in the dissolved state. When the composition makes contact with water (saliva) in (or on) the enamel, the composition is diluted with water (saliva) and then the instantly recited ingredient (B) separates out from the dissolved state and precipitates in the enamel.

The separated ingredient (B) prevents the tooth whitening ingredient, which has penetrated into the enamel, from easily leaching out so that the tooth whitening ingredient is not easily replaced by water (saliva). As a result, the whitening effect endures for a long time until the tooth whitening ingredient which has penetrated into the enamel is gradually replaced by water in saliva, so that the treated teeth resorts to its original color.

Therefore, by the inventive tooth whitening set and the method, it has been possible to improve the above problem of the tooth whitening method of Oniki et al. The unexpected superiority of the present invention is also evident from the results of Comparative Example No. 1, wherein the ingredient (B) is not incorporated into the comparative composition.

Furthermore, the inventive nonaqueous gel composition is retained on teeth for 1 to 120 minutes in order to avoid the contact of saliva to teeth. If tooth brushing is conducted for the inventive nonaqueous gel composition as in the conventional dentifrice compositions at the beginning of use, the infiltration of the inventive tooth whitening ingredient into the tooth

enamel would not be attained due to a dilution of the composition since saliva gets into the composition. Therefore, the composition is retained by a special tool (as claimed) for at least one minute so that the composition is not diluted by saliva. After the tooth whitening action, the inventive composition may be wiped off with tissue paper, and the tooth whitening ingredient in the enamel is replaced by water from saliva, thereby going back to the original color of the enamel reversibly.

Applicable U.S. Case Law

M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 set forth some rationales that were set established in the recent decision of *KSR International Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (U.S. 2007).

Distinctions over the Combination of Oniki et al. and Takeda et al.

The cited primary reference of Oniki et al. (WO 03/030851) fails to disclose the use of the mentioned substance or ingredient (B) and the advantages of the present invention. This is a

major deficiency of Oniki et al.

Further, the cited secondary reference of Takeda et al. (or U.S. 2001/0007652) does not account for the deficiencies of Oniki et al., and Takeda et al. disclose a dentifrice composition for imparting gloss on teeth comprising shellac or wax, and further has propylene glycol and/or glycerin as a solvent. Also, in Takeda's composition, these polyols are not used as the tooth whitening ingredient.

Moreover, Takeda's composition is applied to the teeth as any conventional application method of dentifrice composition by brushing. And besides the Takeda composition being used at the beginning of brushing teeth, the infiltration of polyols into the tooth enamel would not be attained due to a dilution of the Takeda composition by invasion of saliva into its composition. This is unlike the present invention as mentioned above.

Further, Takeda fails to disclose and teach the application of the nonaqueous gel composition by using the special tool like the present claimed sets and methods.

In this regard, combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art. *United States v. Adams*, 383 U.S. 39, 51-52, 148 USPQ 479, 483-84 (1966); *see also* M.P.E.P. § 2143. In other words, Oniki et al. is being improperly combined with Takeda et al. because, e.g., infiltration of polyols into the tooth enamel cannot be attained since teeth are brushed with the Takeda et al. composition.

Furthermore, in Takeda's composition, the wax or shellac covers the surface of the teeth, thereby smoothing the surface thereof, and it has been considered that irregular reflection of light is prevented, and so, good gloss, brightness and luster can be imparted to the teeth (see its page

3, paragraph (0039)). Takeda's wax and shellac would rapidly turn to a state of precipitation on the surface of the teeth, thereby covering the teeth surface. Thus, in Takeda, the infiltration of polyols would not be attained due to cover that is generated from precipitated wax or shellac on the surface of the teeth. This is also a different way of attaining a whitening effect compared to the present invention. Moreover, the precipitated wax and shellac on the surface of the teeth in Takeda would be brittle and be easily removed. The features and advantages of the present invention could not be achieved.

Applicants note that the Federal Circuit has held: "If references taken in combination would produce a 'seemingly inoperative device,' we have held that such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness." See *McGinley v. Franklin Sports Inc.*, 60 USPQ2d 1001, 1010 (CAFC 2001)(citing *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969) (references teach away from combination if combination produces seemingly inoperative device) and *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (inoperable modification teaches away)). Here, the Takeda composition forms a coating of wax or shellac on the teeth, wherein the polyols would not even infiltrate. Coupled with how Oniki et al. does not even disclose instantly claimed substance (B), the cited combination of references is improper.

In anything, substantial hindsight reconstruction is being used to form the instant rejection. However, the application of hindsight is inappropriate where the prior art does not suggest that the claimed compound/composition could reasonably be expected to manifest the properties and advantages that were found for the claimed invention. *Sanofi-Synthelabo*, 89 USPQ2d 1370, 1379 (Fed. Cir. 2008) (citing *Graham v. John Deere Co.*, 383 U.S 1, 36

(cautioning against hindsight whereby the teachings of the invention are read into the prior art) and *KSR International Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (recognizing “hindsight bias” and “ex post reasoning” as inappropriate in determination of obviousness)). That is the case here.

Applicants further note that Takeda's wax or shellac which would not penetrate into the teeth, especially into the interrod substance (interstices of the tooth enamel rod), in the dissolved state. Again, the action by using the wax or shellac in the Takeda's dentifrice composition is different from the action by using the ingredient (B) in the inventive gel composition. Therefore, Takeda's tooth glossing action is different from the tooth whitening action of the inventive gel composition. Accordingly, both Oniki et al. and Takeda et al. fail to disclose and teach all features and advantages of the present invention and are improperly combined.

As is evident from the above discussion, one of ordinary skill in the art would not have the proper rationale or reason to combine Oniki et al. with Takeda et al. because of the types of compositions being employed, as well as the different actions on teeth. Even if Oniki et al. is somehow combined with Takeda et al., it would be impossible for the skilled artisan to reasonably expect any such benefit of using the Takeda et al. wax/shellac in Oniki et al.'s composition based on the disclosure in these two references. Therefore, Applicants respectfully submit that the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue and evaluating any evidence of secondary considerations, weigh in Applicants' favor. Reconsideration and withdrawal of this rejection is respectfully requested.

Applicants also add that the cited references fail to disclose new claim 41, including the recited substance (B).

***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez, Registration No. 48501 at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

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